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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,120	11/29/2004	Masaru Yamakoshi	1516-0126PUS1	3292
2292 7590 12/04/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER MARTIN, PAUL C	
			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			12/04/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,120	<b>Applicant(s)</b> YAMAKOSHI ET AL.	
	<b>Examiner</b> Paul C. Martin	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 14, 28 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 14, 28 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-9, 13, 14, 28 and 31-33 are pending in this application and were examined on their merits.

The rejection of Claims 1-5, 8, 9, 14, 30 and 31 under 35 U.S.C. § 102(b) as being anticipated by Takatsuma *et al.* (JPO 2001190299A) has been withdrawn due to the Applicants amendments to the Claims filed 09/21/07.

The rejection of Claims 1-9, 14, 18-20, 27, 28, 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Takatsuma *et al.* (JPO 2001190299A) in view of Tazoe *et al.* (US 6,309,852 B1) has been withdrawn due to the Applicants amendments to the Claims filed 09/21/07.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 13, 14, 28 and 31-33 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Newly amended claims 1 and 31 contain the new limitations wherein concentration(s) of myo-inositol at characteristic values or higher than characteristic values of 0 to 20 micrograms myo-inositol per milligram creatinine when measured as an increasing amount of myo-inositol excreted in the urine after 75 grams glucose load is indicative of a subject having mild impaired glucose tolerance or an insulin secretory defect. One of ordinary skill in the art would not be able to use the instant invention because no time periods are specified in the method, though the disclosure repeatedly refers to time limits for collecting and analyzing specimens (See Specification, Pg. 10, Lines 1-3 and Table 3). Obviously, the invention relies on the performance of the method at critical time periods as performance of the method at a time of 24 hours or even several days after a 75 gram glucose load would miss the myo-inositol excreted in the urine.

Further, the reference refers to the comparison of myo-inositol per milligram creatinine, yet nowhere in the instant method is a measurement of creatinine performed. One would not be able to use an invention requiring a comparison to a quantity which was never determined. Finally, the concentration of myo-inositol is referred to by characteristic values or higher than characteristic values of 0 to 20 micrograms per mg creatinine. The characteristic values are never explained or explicitly defined in the methods and the value which is higher than the characteristic values of 0 to 20 micrograms per mg creatinine is essentially a limitless value extending into infinity beyond 20 micrograms per mg creatinine. One of ordinary skill in the art at the time of the invention would not be able to practice the invention without knowing what time periods are required to perform the method, a step of measuring the creatinine level as a basis for comparison and without knowing what the characteristic values are and what the definition of the upper limits of the characteristic values specifically encompass. Claims 2-9, 13, 14, 28, 32 and 33 are rejected as being dependent upon rejected claims 1 and 31.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-33 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites the limitation "the urine" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 32 and 33 are rejected as being dependent upon rejected Claim 31.

### ***Conclusion***

No Claims are allowed.

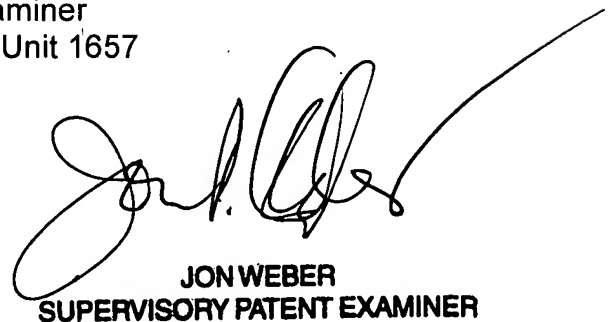
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

11/23/07



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**